

INFORMED CONSENT FORM

(15 September 2017)

Randomized Controlled Field Trial of a Probiotic to assess its role in the prevention or improvement of diarrhea and constipation in Vietnam children

Information to be provided at the community and individual level:

Diarrheal diseases are a major health problem. In clinical studies in other countries, this probiotics have been shown to protect against diarrheal diseases, with no adverse effects. We are conducting a study of this probiotics in Vietnam. We are asking the parents of children who are 3-5 year of age your community to drink this probiotics. The purpose of this study is to assess the usefulness of the probiotics in preventing diarrheal diseases and constipation in your community.

We request your permission to enroll your child in this study. For the purpose of this study, your child will be asked to intake 65 ml of this drink every day for 12 weeks. During the next 4 weeks, if your child develops diarrhea, we request that you go to one of the Hospital: commune station Doctors at commune stations are collaborate to provide service for appropriate counseling and treatment during the time of trial. And doctors at district hospitals and Thanh Hoa province will be collaborated to treat with severe cases when you are referred to. You will be asked to provide a stool sample or rectal swab of your child and will be given treatment. At these Outposts or the hospital, the stool sample will be collected to investigate the cause of diarrhea. If necessary, your child will be referred for hospitalization. The laboratory examination will be free of charge. Also, the treatment according to standard guidelines for diarrhea will be provided free or if you pay for it, you will be reimbursed. Child's height, weight and mid upper arm circumference measurements will also be taken at the beginning, 4, 8, 12 weeks and at 16 weeks. Investigators from NIN will undertake height and weight measurements at these 5 points.

The information that you provide will be kept confidential. The private information will store your records in a safe place (at NIN). Our doctors (at Thanh Hoa Hospital, Yen Dinh Hospital, Nong Cong Hospital, and Health Station) will be available at your local to answer any questions and to provide medical advice on diarrhea or constipation. If you have questions about this program, your rights or about any adverse reaction related to your child's participation, please contact either Dr. Mai or you can directly come to the Hospital or bring your child to Hospital for medical care (Thanh Hoa Hospital, Yen Dinh Hospital, Nong Cong Hospital, and Health Station).

The results of this study will improve our knowledge about this nutritional drink and thus benefit society. You are free to accept or reject our proposal to enroll your child in this study. Even after enrolment you will be able to withdraw yourself from the study at any time. You will also receive a copy of this form to review. If you agree to our proposal to enroll your child in the study, please indicate this by putting your signature or the impression of your left thumb below. Thank you.

Name of Subject: _____ Household # _____ Individual # _____

Signature/left thumb impression of parents:

Name of parents :

Date:

Signature of witness:

Signature of the investigator/ designee:

Name:

Name of investigator/designee:

Date:

Date: